

S/N 09/689136



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John F. Engelhardt et al. Examiner: Daniel M Sullivan
Serial No.: 09/689136 Group Art Unit: 1636
Filed: October 12, 2000 Docket: 875.032US1
Title: COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(c)(2), Applicants have included the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 19-0743.

01/16/2004 SSANDARA 00000012 09689136
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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

JOHN F. ENGELHARDT ET AL.

By their Representatives,

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Date

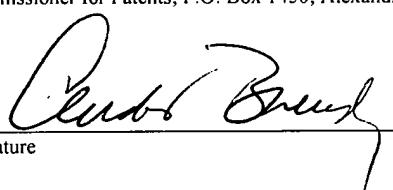
January 17, 2004 By Janet E. Embretson
Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of January, 2004.

Name

Candis B. Buending

Signature



Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known						
		Application Number 09/689136 Filing Date October 12, 2000 First Named Inventor Engelhardt, John Group Art Unit 1636 Examiner Name Sullivan, Daniel						
		Attorney Docket No: 875.032US1						
		Sheet 1 of 2						

US PATENT DOCUMENTS						
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-2002/0197237	12/26/2002	Engelhardt, J. , et al.	424	93.2	01/22/2002
	US-20020076754	06/20/2002	Sun, Liangwu , et al.	435	69.1	04/20/2001
	US-20020131956 A1	09/19/2002	Walsh, C. E., et al.	424	93.2	03/12/2002
	US-5,843,742	12/01/1998	Natsoulis, G. , et al.	435	172.3	09/08/1995
	US-6,156,303	12/05/2000	Russell, D. W., et al.	424	93.2	06/11/1997
	US-6,221,349	04/24/2001	Couto, Linda B., et al.	424	93.2	07/30/1999
	US-6,287,569	09/11/2001	Kipps, T. J., et al.	424	199.1	04/06/1998
	US-6,436,392	08/20/2002	Engelhardt, John F., et al.	424	93.2	03/25/1999
	US-6,544,786	04/08/2003	Xiao, Xiao , et al.	435	325	10/13/2000

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
	WO-01/83692	11/08/2001	Hildinger, M. , et al.	C12 N		

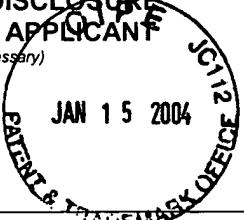
OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
		BERNS, K. I., et al., "Biology of Adeno-associated Virus", In: <u>Current Topics in Microbiology and Immunology</u> , 218, Springer-Verlag, Berlin: R.W. Compans, et al., (Eds.),(1996),pp. 1-23				
		BERNS, K. I., "Parvovirus Replication", <u>Microbiological Reviews</u> , 54 (3), (Sept. 1990),pp. 316-329				
		DUAN, Dongsheng , et al., "Circular intermediates of recombinant adeno-associated virus having defined structural characteristics responsible for long-term episomal persistence in muscle tissue", <u>J. of Virology</u> , 72 (11), (Nov. 1998),pp. 8568-8577				
		DUAN, Dongsheng , et al., "Endosomal processing limits gene transfer to polarized airway epithelia by adeno-associated virus", <u>Journal of Clinical Investigation</u> , vol. 105, number 11, (June 2000),1573-1587				
		DUAN, Dongsheng , et al., "Structural Analysis of adeno-associated virus transduction circular intermediates", <u>Virology</u> , 261 (1), (Aug. 1999),pp. 8-14				
		DUAN, Dongsheng , et al., "Structural and functional heterogeneity of integrated recombinant AAV genomes", <u>Virus Research</u> , 48 (1), (Jan. 1997),pp. 41-56				
		ENGELHARDT, John , et al., "Adeno'Associated Virus Vectors", <u>U.S. Provisional Application</u> SN 60/086,166, FILED May 20, 1998 (875.005PRV).				
		ENGELHARDT, John , et al., "Compounds And Methods To Enhance Adeno-Associated Virus Transduction", <u>U.S. Provisional Application</u> SN 60/138,188, filed June 8, 1999 (875.012PRV).				

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		<i>Complete if Known</i>	
		Application Number	09/689136
		Filing Date	October 12, 2000
		First Named Inventor	Engelhardt, John
		Group Art Unit	1636
		Examiner Name	Sullivan, Daniel
Sheet 2 of 2		Attorney Docket No: 875.032US1	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ENGELHARDT, John , et al., "Compounds And Methods To Enhance Adeno-Associated Virus Transduction", <u>U.S. Provisional Application SN 60/201,089 filed May 2, 2000 (875.032PRV)</u> .	
		ENGELHARDT, John , Et Al., "Enhancement Of Muscle Gene Delivery With Pseudotyped Aav-5 Correlates With Myoblast Differentiation", <u>U.S. Provisional Application SN 60/305,204 filed July 13, 2001 (875.053PRV)</u> .	
		ENGLEHARDT, John , et al., "Adeno-Associated Virus Vectors", <u>Patent Application Serial Number 10/054665, 875.007us2 (January 22, 2002), 141 pages</u>	
		ENGLEHARDT, John , et al., "Adeno-Associated Virus Vectors and Uses Thereof", <u>Patent Application Serial Number 09/684554, filed October 6, 2000, (875.024us1); 141 pages</u>	
		ENGLEHARDT, John , "Compounds And Methods For Pharmico-Gene Therapy Of Epithelial Sodium Channel Associated Disorders", <u>U.S. Provisional Application SN 60/512,347 filed October 16, 2003 (875.085PRV)</u> .	
		ENGLEHARDT, John , et al., "Compounds And Methods To Enhance Raav Transduction", <u>U.S. Provisional Application SN 60/459,323 filed March 31, 2003 (875.074PRV)</u> .	
		ENGLEHARDT, John , et al., "Pseudotyped Adeno-Associated Viruses And Uses Thereof", <u>U.S. Patent Application SN 10/194,421 filed July 12, 2002 (875.053US1)</u> .	
		QING, K. , et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro and Murine Tissues In Vivo", <u>Journal of Virology, 72 (2), (Feb. 1998), pp. 1593-1599</u>	
		RENDAHL, Katherine G., et al., "Regulation of gene expression in vivo following transduction by two separate rAAV vectors", <u>Nature Biotechnology (1998) Vol. 16, 757-761</u>	
		WESTFALL, T. D., et al., "The ecto-ATPase inhibitor ARL 67156 enhances parasympathetic neurotransmission in the guinea-pig urinary bladder", <u>European Journal of Pharmacology, 329, (1997), pp. 169-173</u>	
		YAN, ZIYING , et al., "Trans-splicing vectors expand the utility of adeno-associated virus for gene therapy", <u>PNAS, 97 (12), (June 6, 2000), pp. 6716-6721</u>	

EXAMINER

DATE CONSIDERED

S/N 09/689136

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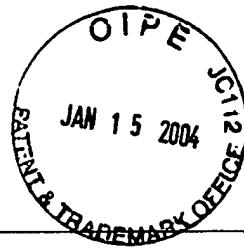
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Filed: October 12, 2000 Docket: 875.032US1
Title: COMPOUNDS AND METHODS TO ENHANCE RAAV TRANSDUCTION

COMMUNICATION CONCERNING RELATED APPLICATIONS

Commissioner for Patents
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Alexandria, VA 22313-1450

Applicants would like to bring to the Examiner's attention the following related applications in the above-identified patent application:

<u>Serial/Patent No.</u>	<u>Filing Date</u>	<u>Attorney Docket</u>	<u>Title</u>
60/086166	May 20, 1998	875.005PRV	ADENO-ASSOCIATED VIRUS VECTORS
09/276625 6436392	March 25, 1999	875.007US1	ADENO-ASSOCIATED VIRUS VECTORS
10/054665	January 22, 2002	875.007US2	ADENO-ASSOCIATED VIRUS VECTORS
60/138188	June 8, 1999	875.012PRV	COMPOUNDS AND METHODS TO ENHANCE ADENO-ASSOCIATED VIRUS TRANSDUCTION
09/684554	October 6, 2000	875.024US1	ADENO-ASSOCIATED VIRUS VECTORS AND USES THEREOF
60/201089	May 2, 2000	875.032PRV	COMPOUNDS AND METHODS TO ENHANCE ADENO-ASSOCIATED VIRUS TRANSDUCTION
60/305204	July 13, 2001	875.053PRV	ENHANCEMENT OF MUSCLE GENE DELIVERY WITH PSEUDOTYPED AAV-5 CORRELATES WITH MYOBLST DIFFERENTIATION



10/194421	July 12, 2002	875.053US1	PSEUDOTYPED ADENO- ASSOCIATED VIRUSES AND USES THEREOF
60/459323	March 31, 2003	875.074PRV	COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION
60/512347	October 16, 2003	875.085PRV	COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED DISORDERS

Respectfully submitted,

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Date JANUARY 12, 2004

By Janet E. Embretson
Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of January, 2004.

Candis B. Buending
Name

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